DOI: 10.1177/2050640620972959

LETTER TO THE EDITOR

ueg journal WILEY

Lack of evidence for the use of ustekinumab for acute severe ulcerative colitis

Dear Editor,

We read with interest clinical outcomes with ustekinumab as rescue treatment in therapy-refractory or therapy-intolerant ulcerative colitis (UC),[1] which aimed to assess the use of ustekinumab as rescue therapy for severe colitis. This retrospective analysis of 19 patients reported clinical remission of 53% at 1 year following ustekinumab therapy.

Our concern with this study is it defines acute severe ulcerative colitis (ASUC) using the colitis activity index (CAI) with a median score of 8.5, which would indicate either very mild or, at the very worse, moderate disease and hence this cannot be defined as acute severe colitis. Significantly, this score has yet to be validated as a tool to accurately define severe colitis and hence other validated scores would have provided more accuracy to the severity of the UC. We also note that inclusion to the study was for those patients who had not induced adequate clinical response. The baseline data however state that at least six of the patients in this study had CAI scores of 6 or less; clearly far from scores that would imply acute severe UC. Three of the patients that were included in this study were in remission and hence would not be considered ASUC. Moreover, it is difficult to appreciate why patients in, or approaching, clinical remission were commenced on ustekinumab.

A further significant point is reference to remission in acute colitis. In the Unifi studies, remission is defined at Week 8 in the induction phase and at Week 44 in the maintenance phase of the study.[2] It is, therefore, difficult to compare outcomes with the UNIFI study when outcomes at 8 weeks were not available. Furthermore, much stricter criteria were used in the UNIFI study to define moderate-to-severe colitis and hence we feel the results are not comparable. One final concern is the definition of remission, with 1 of the 10 who achieved remission still requiring steroids at the end of 12 months. Usually, steroid-free remission is the gold standard used to define remission in most studies.

We believe this study highlights that ustekinumab may be a useful second- or third-line therapy for mild-to-moderate UC to help maintain remission, but feel that this manuscript does not demonstrate that ustekinumab can be used as rescue treatment for ASUC. Crucially, given that the study title and aims could potentially lead to unsafe/unproven treatment strategies for patients with ASUC, we would recommend that the journal considers publishing a corrigendum for clarification.

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REFERENCES

1. Ochsenkühn T, Tillack C, Szokodi D, et al. Clinical outcomes with ustekinumab as rescue treatment in therapy- refractory or therapy-intolerant ulcerative colitis. *United Eur Gastroenterol J*. 2020;8:91–8.
2. Sands BE, Sandborn WJ, Panaccione R, et al. Ustekinumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med*. 2019;381:1201–14.